ASSEMBLY COMMITTEE ON HEALTH AND HEALTHCARE REFORM

Representative, Jon Richards, Chair

Joint Testimony of Health Care Providers and Provider Organizations
2009 Assembly Bill 651
Relating to the donation of drug samples to charitable organizations
Room 417, North, State Capitol
Wednesday, January 20, 2010, 10:30 a.m.

Chairperson Richards and members of the Committee, thank you for the opportunity to submit testimony in support of 2009 Assembly Bill 651.

We urge passage of AB 651, which seeks to remove barriers that currently restrict practitioners' ability to donate unused prescription drug samples to the 50 community clinics and federally qualified health centers located throughout the State of Wisconsin.

Community clinics and health centers provide valuable health care safety net services to vulnerable populations by providing comprehensive and community oriented primary health care services, while also decreasing expensive and unnecessary emergency room utilization. Wisconsin has 17 community health centers with over 70 sites state-wide.

Prescription medications serve a vital role in keeping patients healthy and are often prescribed when patients receive health services at community clinics and health centers, such as for well-child, prenatal and perinatal services and chronic disease management. However, it is often challenging to meet the growing need for free or low cost medications, especially in the community clinic or health center setting.

AB 651 presents an opportunity to expand the availability of medications in community clinics by allowing licensed Wisconsin practitioners to donate unused or excess prescription drug samples to clinics and centers that serve populations in need.

If passed, AB 651 would treat community clinics and health centers similar to the current state drug repository donation process. Under AB 651, any community clinic and health center organized as a 501(c)(3) corporation qualifies federally to receive donated drug samples directly from practitioners or other charitable organizations.

The donation process under the federal program is safe and secure: no controlled substances can be donated; stringent recordkeeping requirements are in place; and donations must be in their unopened, original containers, which are examined by a pharmacist or practitioner, to assure they are not expired or adulterated.

Please help us to utilize these valuable additional means to better serve our patients in need by passing AB 651.

Thank you.

Gordon Derzon
Interim Chief Executive Officer
Access Community Health Centers

Rachel Roller
Vice President, Government Affairs
Aurora Health Care

Patrick Brown
Executive Director
Badger Association of the Blind
and the Visually Impaired

Paul Westrick
VP, Mission Integration & Advocacy
Columbia St. Mary's

Lynn Breedlove
Executive Director
Disability Rights Wisconsin

N. Lee Carroll
Executive Director
Health Care for the Homeless of Milwaukee

Tom Hlavacek
Co-Chair
Make It Work Milwaukee Coalition

H. Bruce Kruger
Executive Vice President
The Medical Society of Milwaukee County

Kari Lerch
Co-Chair
Milwaukee Health Coalition

Lynne J. Oelke
President & CEO
St. Catherine Residence

Tom Petri
Director of Policy and Communications
Wisconsin Primary Health Care Association

Melinda Kiltz
Trust Coordinator
ARC of Greater Milwaukee

Steve Ohly
Aurora Walker's Point Community Clinic

Barbara A. Horner-Ibler
Medical Director
The Bread of Healing Clinic

David R. Riemer
Director of Policy & Planning
Community Advocates Public Policy
Institute

Jacqueline Sills-Ware
Co-Convenor
The Free Clinic Collaborative

Barb Tylenda
Executive Director
Health Care Network, Inc.

Barbara Beckert
Co-Chair
Make It Work Milwaukee Coalition

Joy Tapper
Milwaukee Health Care Partnership

Tom Engels
Vice President
Pharmacy Society of Wisconsin

Jenni Sevenich
CEO
Westside Healthcare Association, Inc.

Bill Bazan
VP, Metro Milwaukee
Wisconsin Hospital Association

P.O. Box 281496 • Nashville, TN • 37228
P: 615-736-5075 • F: 615-736-5624
Toll Free: 888-428-HOPE (4673)

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Room 417, North, State Capitol
Wednesday, January 20, 2010, 10:30 a.m.

Chairperson Richards and members of the Committee, thank you for allowing me an opportunity to submit testimony in support of 2009 Assembly Bill 651 (AB 651).

I represent the Dispensary of Hope, a not-for-profit social venture that specializes in helping communities leverage surplus donated medicine as a source of sustainable pharmaceutical access for low-income and underinsured populations. I support AB 651 because it seeks to remove barriers that currently restrict practitioners' ability to donate unused prescription drugs to community clinics and federally qualified health centers located throughout the State of Wisconsin.

From our experience, let me offer three important reasons to support AB 651:

a) Free clinics, community health centers, and other safety net providers do not receive the same level of sample medications from pharmaceutical manufactures; therefore practitioners in safety net providers are not able to trial medications or provide initial free products in the same fashion as their peers in private practices.

b) More than 10% of sample medications provided to private practices are considered surplus and are a source that could be re-directed to safety net providers. Furthermore, samples represent just one of many sources of surplus medicine in the pharmaceutical supply chain which represents billions of dollars of surplus medications.

c) This solution has already been proven in at least 13 other states to the benefit of safety net providers and their patients as well as manufactures who are realizing the value of a more efficient supply chain. This solution has been approved by 20 pharmacy boards for its robust process integrity. To ensure "chain of custody" tracking, web-based tools and processes support the safety and security of drug donations, storage, ordering, and dispensing.

Over the past months, the Dispensary of Hope has worked with the leadership of several of the state's hospitals, community health centers, and patient advocates to share our expertise to accomplish their vision for Wisconsin. Founded in 2003 by a physician and group of healthcare businessmen who envisioned how better stewardship of America's billions of dollars of surplus medicine could provide a creative solution for patients that can't afford their medications, the Dispensary of Hope now supports similar efforts across thirteen states, including: Alabama, Arkansas, Georgia, Indiana, Kentucky, Louisiana, Michigan, Mississippi, Missouri,

P.O. Box 281496 • Nashville, TN • 37228
P: 615-736-5075 • F: 615-736-5624
Toll Free: 888-428-HOPE (4673)

New York, Pennsylvania, Tennessee, and Texas. The Dispensary of Hope is licensed with the Board of Pharmacy in each of these states plus an additional seven states that plan on participating in 2010.

To ensure the highest levels of process integrity, as set forth by the Food and Drug Administration and State pharmacy boards, the Dispensary of Hope has developed process and web tools to provide chain of custody tracking through our eHope system and turn key donation and shipping partnership with UPS.

If passed, AB 651 would treat community clinics similar to the current state drug repository donation process. Under AB 651, any organization that is legally providing health care and is organized as a 501(c)(3) corporation qualifies under federal law to receive donated drugs directly from practitioners or other charitable organizations.

Eligible entities would be required to abide by federal donation guidelines. The donation process under the federal program is safe and secure: no controlled substances can be donated; stringent recordkeeping requirements are in place; and donations must be in their unopened, original containers, which are examined by a pharmacist or practitioner, to assure they are not expired or adulterated.

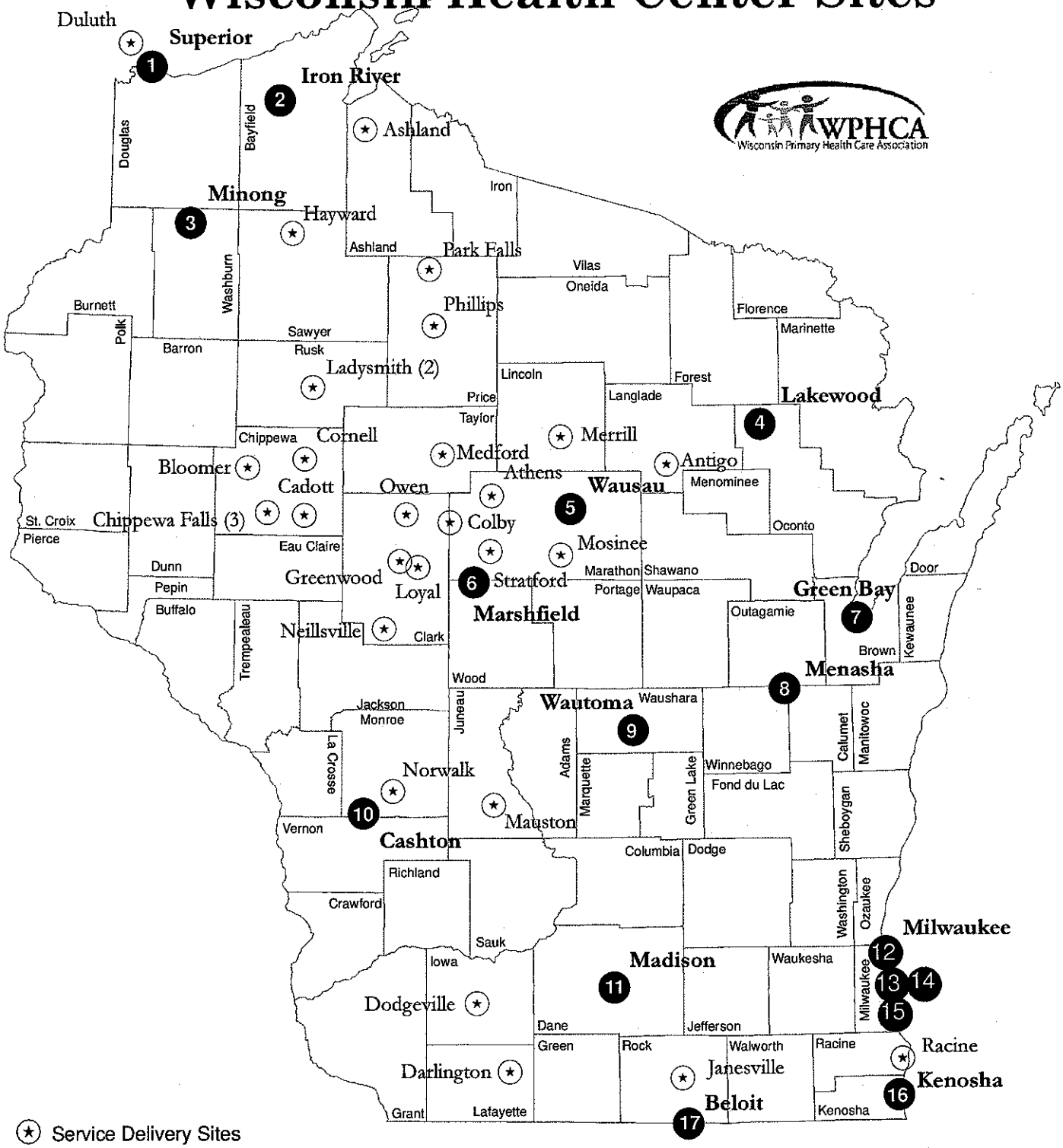
Please help us to utilize these valuable additional means to better serve patients in need by passing AB 651.

Thank you.

Daniel J. Simpson

Chief Development Officer
Dispensary of Hope

Wisconsin Health Center Sites



WPHCA
Wisconsin Primary Health Care Association

★ Service Delivery Sites

1. Lake Superior Community Health Center, Superior
2. The Lakes Community Health Center, Iron River
3. North Woods Community Health Centers, Minong
4. Northern Health Centers, Inc., Lakewood
5. Bridge Community Health Clinic, Wausau
6. Family Health Center of Marshfield, Marshfield
7. N.E.W. Community Clinic, Green Bay (7 Sites)
8. Fox Cities Community Health Center, Menasha
9. Family Health/La Clinica, Wautoma
10. Scenic Bluffs Community Health Centers, Cashton
11. Access Community Health Center, Madison (3 Sites)
12. Health Care for the Homeless of Milwaukee, Milwaukee (6 Sites)
13. Milwaukee Health Services, Inc., Milwaukee (3 Sites)
14. Westside Healthcare Association, Inc., Milwaukee (2 Sites)
15. Sixteenth Street Community Health Center, Milwaukee (3 Sites)
16. Kenosha Community Health Center, Kenosha
17. Community Health Systems. Inc.

Current as of January, 2010

STATE REPRESENTATIVE
KRISTEN DEXTER
WISCONSIN STATE ASSEMBLY
68TH DISTRICT

Testimony from Representative Kristen Dexter
January 20, 2010
Committee on Health and Healthcare Reform
In support of AB 651

Mr. Chairman, Committee members, thank you for convening today to hold this hearing on Assembly Bill 651, relating to the donation of prescription drug samples to free and community clinics throughout our state.

Prescription medications serve a vital role in keeping patients healthy and are often prescribed in the community clinic setting. However, as the number of patients swell and clinics come under more financial strain, it becomes increasingly difficult to meet the growing need for free or low cost medications.

This bill would allow licensed WI practitioners to donate unused or excess prescription drug samples to clinics that serve populations in need. Current law regulates the wholesale distribution of prescription drugs (defined as the distribution of a prescription drug to a person other than a consumer or patient.) This bill adds an exception to the definition of *wholesale distribution* so that licensed WI practitioners may donate directly to charitable institutions. This is similar to the exception that allows a cancer and chronic disease drug repository.

Current Wisconsin law surrounding sample donation guidelines is different than the laws within the federal Prescription Drug Marketing Act. Over 10 years ago the federal government recognized the importance of providers' practice of charitable donations of unused medications. This bill will allow WI law to accurately reflect what is already in federal statutes. A copy of the statutes has been provided to members of the committee.

Any community clinic organized as a 501(c)(3) corporation qualifies *federally* to receive donated drug samples from practitioners or other charitable organizations. The current donation process is safe and secure: It requires that:

1) No controlled substances may be donated;
2) Stringent recordkeeping requirements are in place,
3) Donations be in their unopened, original containers. The containers are examined by a pharmacist or practitioner to assure they are not expired or adulterated.

The Chippewa Valley Free Clinic in my hometown of Eau Claire has provided medical services to 40% more patients this year than last. The spike in patients, coupled with restrictive donation regulations, is creating an environment that is not conducive to supplying clinics like the one in Eau Claire with the medications they need.

Removing the wholesale distributor barrier for private sector donations to community clinics will further advance the state's intent of expanding health care access for Wisconsin's neediest individuals.

Again, thank you for convening today and I hope that we can work together to pass Assembly Bill 651.

State Capitol, PO Box 8952, Madison, WI 53708 • (608) 266-9172 • FAX: (608) 282-3668
Toll-free: (888) 534-0068 • E-mail: rep.dexter@legis.wi.gov

and the results of the investigation, not later than 30 days after the date of the initial notification in paragraph (a)(1) of this section.

(b) *Significant loss or known theft of drug samples.* A manufacturer or authorized distributor of record that distributes drug samples or a charitable institution that receives donated drug samples from a licensed practitioner shall:

(1) Notify FDA, by telephone or in writing, within 5 working days of becoming aware of a significant loss or known theft;

(2) Immediately initiate an investigation into the significant loss or known theft; and

(3) Provide FDA with a complete written report, including the reason for and the results of the investigation, not later than 30 days after the date of the initial notification in paragraph (b)(1) of this section.

(c) *Conviction of a representative.* (1) A manufacturer or authorized distributor of record that distributes drug samples shall notify FDA, by telephone or in writing, within 30 days of becoming aware of the conviction of one or more of its representatives for a violation of section 503(c)(1) of the act or any State law involving the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(2) A manufacturer or authorized distributor of record shall provide FDA with a complete written report not later than 30 days after the date of the initial notification.

(d) *Selection of individual responsible for drug sample information.* A manufacturer or authorized distributor of record that distributes drug samples shall inform FDA in writing within 30 days of selecting the individual responsible for responding to a request for information about drug samples of that individual's name, business address, and telephone number.

(e) *Whom to notify at FDA.* Notifications and reports concerning prescription human drugs shall be made to the Division of Prescription Drug Compliance and Surveillance (HFD-330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. Notifications and reports concerning prescription human biological products shall be made to the Division of Inspections and Surveillance (HFM-650), Office of Compliance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852.

§ 203.38 Sample lot or control numbers; labeling of sample units.

(a) *Lot or control number required on drug sample labeling and sample unit label.* The manufacturer or authorized distributor of record of a drug sample shall include on the label of the sample unit and on the outside container or packaging of the sample unit, if any, an identifying lot or control number that will permit the tracking of the distribution of each drug sample unit.

(b) *Records containing lot or control numbers required for all drug samples distributed.* A manufacturer or authorized distributor of record shall maintain for all samples distributed records of drug sample distribution containing lot or control numbers that are sufficient to permit the tracking of sample units to the point of the licensed practitioner.

(c) *Labels of sample units.* Each sample unit shall bear a label that clearly denotes its status as a drug sample, e.g., "sample," "not for sale," "professional courtesy package."

(1) A drug that is labeled as a drug sample is deemed to be a drug sample within the meaning of the act.

(2) A drug product dosage unit that bears an imprint identifying the dosage form as a drug sample is deemed to be a drug sample within the meaning of the act.

(3) Notwithstanding paragraphs (c)(1) and (c)(2) of this section, any article that is a drug sample as defined in section 503(c)(1) of the act and § 203.3(i) that fails to bear the label required in this paragraph (c) is a drug sample.

§ 203.39 Donation of drug samples to charitable institutions.

A charitable institution may receive a drug sample donated by a licensed practitioner or another charitable institution for dispensing to a patient of the charitable institution, or donate a drug sample to another charitable institution for dispensing to its patients,

provided that the following requirements are met:

(a) A drug sample donated by a licensed practitioner or donating charitable institution shall be received by a charitable institution in its original, unopened packaging with its labeling intact.

(b) Delivery of a donated drug sample to a recipient charitable institution shall be completed by mail or common carrier, collection by an authorized agent or employee of the recipient charitable institution, or personal delivery by a licensed practitioner or an agent or employee of the donating charitable institution. Donated drug samples shall be placed by the donor in a sealed carton for delivery to or collection by the recipient charitable institution.

(c) A donated drug sample shall not be dispensed to a patient or be distributed to another charitable institution until it has been examined by a licensed practitioner or registered pharmacist at the recipient charitable institution to confirm that the donation record accurately describes the drug sample delivered and that no drug sample is adulterated or misbranded for any reason, including, but not limited to, the following:

(1) The drug sample is out of date;

(2) The labeling has become mutilated, obscured, or detached from the drug sample packaging;

(3) The drug sample shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;

(4) The drug sample is for a prescription drug product that has been recalled or is no longer marketed; or

(5) The drug sample is otherwise possibly contaminated, deteriorated, or adulterated.

(d) The recipient charitable institution shall dispose of any drug sample found to be unsuitable by destroying it or by returning it to the manufacturer. The charitable institution shall maintain complete records of the disposition of all destroyed or returned drug samples.

(e) The recipient charitable institution shall prepare at the time of collection or delivery of a drug sample a complete and accurate donation record, a copy of which shall be retained by the recipient charitable institution for at least 3 years, containing the following information:

(1) The name, address, and telephone number of the licensed practitioner (or donating charitable institution);

(2) The manufacturer, brand name, quantity, and lot or control number of the drug sample donated; and

(3) The date of the donation.

(f) Each recipient charitable institution shall maintain complete and accurate records of donation, receipt, inspection, inventory, dispensing, redistribution, destruction, and returns sufficient for complete accountability and auditing of drug sample stocks.

(g) Each recipient charitable institution shall conduct, at least annually, an inventory of prescription drug sample stocks and shall prepare a report reconciling the results of each inventory with the most recent prior inventory. Drug sample inventory discrepancies and reconciliation problems shall be investigated by the charitable institution and reported to FDA.

(h) A recipient charitable institution shall store drug samples under conditions that will maintain the sample's stability, integrity, and effectiveness; and will ensure that the drug samples will be free of contamination, deterioration, and adulteration.

(i) A charitable institution shall notify FDA within 5 working days of becoming aware of a significant loss or known theft of prescription drug samples.

Subpart E—Wholesale Distribution

§ 203.50 Requirements for wholesale distribution of prescription drugs.

(a) *Identifying statement for sales by unauthorized distributors.* Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

(1) The proprietary and established name of the drug;